Amended Claims for U.S.S.N. 09/787,229

1. (Amended) A process for the production of an orally administrable multiple-unit sustained-release pharmaceutical composition having controlled agitation-independent release, comprising the steps of (a) combining hydroxypropylcellulose polymer having an average molecular weight of 250 000 to 1 200 000 and a molar degree of substitution of at least 3 in an amount from 40 to 95% by weight with a pharmaceutically active compound to obtain a mixture of polymer and compound; (b) converting said mixture into particles having a diameter of 0.2 to 3.0 mm; and (c) converting said particles into said orally administrable pharmaceutical composition.

2. (Amended) The process according to Claim 1, wherein said polymer is employed in an amount from 45 to 90% by weight.

3. (Amended) The process according to Claim 1, wherein said polymer has an average molecular weight of 350 000 to 1 150 000.

4. (Amended) The process according to Claim 1, wherein said particles have a maximum diameter of 0.5 to 2 mm.

5. (Amended) The process according to Claim 1, wherein said particles are produced by melt extrusion and/or granulation.

6. (Amended) The process according to Claim 1, wherein said particles are converted into said orally administrable pharmaceutical composition by conventional tableting methods.

7. (Amended) The process according to Claim 1, wherein said particles are in the form of pellets, granules, minitablets or grains and wherein said particles are converted into said orally administrable composition by filling said particles into a capsule.

8. (Amended) The process according to Claim 1, further comprising the step of lacquering said particles prior to said step of converting said particles to an orally administrable composition.

12. (Amended) An agitation-independent, multi-unit, sustained release orally administrable pharmaceutical composition, comprising a mixture of hydroxypropylcellulose polymer and a pharmaceutically active compound, wherein said polymer has a molecular weight of between 250,000 and 1,200,000 and a molar degree of substitution of ≥ 3 and is 40-95% by weight of said mixture and further wherein said mixture is granulated to a particle size having a diameter of between 0.2 and 3.0 mm.

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Version with Markings to Show Changes Made

1. (Amended) A p[P]rocess for the production of an orally administrable multiple-unit sustained-release pharmaceutical composition [dose formulation] having controlled agitation-independent release, comprising the steps of [characterized in that the] (a) combining hydroxypropylcellulose [hydrophilic] polymer [HPC] having an average molecular weight of 250 000 to 1 200 000 [is combined in an amount from 40 to 95% by weight, based on the active compound-polymer mixture] and a molar degree of substitution of at least 3 in an amount from 40 to 95% by weight[, as a release-sustaining erosion material,] with [at least one] a pharmaceutically active compound to obtain a mixture of polymer and compound; [and this active compound-polymer combination is converted] (b) converting said mixture into [small] particles having a diameter of 0.2 to 3.0 mm; and (c) converting said particles [these are used in the production of] into [an active oral administration forms and finished medicaments] said orally administrable pharmaceutical composition.

2. (Amended) The p[P]rocess [for the production of a formulation] according to Claim 1, wherein said polymer [characterized in that HPC] is employed in an amount from 45 to 90% by weight.

3. (Amended) The p[P]rocess [for the production of a formulation] according to Claim 1, wherein said polymer has [characterized in that HPC] an average molecular weight of 350 000 to 1 150 000 [is employed].

4. (Amended) The p[P]rocess [for the production of a formulation] according to Claim 1, wherein said particles have [characterized in that the active compound-polymer combination is converted into small particles having] a maximum diameter of 0.5 to 2 mm.

5. (Amended) The p[P]rocess [for the production of formulations] according to Claim 1, wherein said particles [characterized in that the particles for the active

compound-polymer combination] are produced by melt extrusion and/or granulation.

6. (Amended) The p[P]rocess [for the production of formulations] according to Claim 1, wherein said particles are converted into said orally administrable pharmaceutical composition [characterized in that the particles of the active compound-polymer combination are produced] by conventional tableting methods.

7. (Amended) The p[P]rocess [for the production of formulations] according to Claim 1, wherein said particles are [characterized in that the active compound-polymer combination particles are produced] in the form of pellets, granules, minitablets or grains and wherein said particles are converted into said orally administrable composition by [these are filled] filling said particles into a capsule[s in an efficacious dosage].

8. (Amended) The p[P]rocess [for the production of formulations] according to Claim 1, further comprising the step of lacquering said particles prior to said step of converting said particles to an orally administrable composition [characterized in that the active compound-polymer combination particles are additionally lacquered].

12. (Amended) An [Orally administrable multiple-unit sustained-release dose formulations having controlled] agitation-independent, multi-unit, sustained release orally administrable pharmaceutical composition, [obtainable according to Claim 1] comprising a mixture of hydroxypropylcellulose polymer and a pharmaceutically active compound, wherein said polymer has a molecular weight of between 250,000 and 1,200,000 and a molar degree of substitution of ≥ 3 and is 40-95% by weight of said mixture and further wherein said mixture is granulated to a particle size having a diameter of between 0.2 and 3.0 mm.